Customer No. 28880  JUN 1 7 2004 33  Under the Paperwork Reduction and of 1995, no service TRANSMITTAL FORM  (to be used for all correspondence after initial filling)  Total Number of Pages in This Submission	U.S. Paten s are required to respond to a collection Application Number Filing Date First Named Inventor Art Unit Examiner Name Attorney Docket Number	Confirmation No.  PTO/SB/21 (03-03) Approved for use through 04/30/2003. OMB 0651-0031 and Trademark Office; U.S. DEPARTMENT OF COMMERCE of information unless it displays a valid OMB control number.  10/828,419 April 20, 2004 Berchielli, et al Unknown Unknown PC28684A
ENC	LOSURES (Check all that	
Fee Attached  Amendment/Reply  After Final  Affidavits/declaration(s)  Extension of Time Request  Express Abandonment Request  Information Disclosure Statement  Certified Copy of Priority Document(s)  Response to Missing Parts/ Incomplete Application  Response to Missing Parts under 37 CFR 1.52 or 1.53	ORIZATION TO CHARGE T SSARY OR CREDIT ANY O' 5 IS HEREBY GIVEN.	Other Enclosure(s) (please Identify below): Information Disclosure Statement PTO forms SB/08A and SB/08B All Cited An Return Postcard  THE FEE AND ANY ADDITIONAL FEES AS VERPAYMENT TO DEPOSIT ACCOUNT
	OF APPLICANT, ATTORN	ET, OR AGENT
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first class mail in an envelope addressed to:Commissioner for F	ansmitted to the USPTO or deposited v Patents, P.O.Box 1450, Alexandria, VA 22313	with the United <u>States Postal Service with sufficient</u> postage as 1-1450 on this date 6-11-2004
Typed or printed Nancy Dernbach		

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Date

6-11-2004

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Signature

Application No.:

10/828,419

Applicant:

Berchielli, et al

Filed:

April 20, 2004

TC/A.U.:

Ünknown

Examiner:

Unknown

Docket No.:

PC25684A

Customer No.:

28880

Title:

PHARMACEUTICAL COMPOSITIONS OF ATORVASTATIN

## **INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97)**

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Forms PTO/SB/08A and PTO/SB/08B are brought to the attention of the Examiner.

The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 C.F.R. § 1.53(d); or before the mailing of the first Office Action on the merits.

In accordance with 37 C.F.R. § 1.98(a)(2), a copy of each document or other information listed on the enclosed Forms PTO/SB/08A and PTO/SB/08B is provided, except for United States Patents and United States Patent Application Publications.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. § 102 and 103, and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art".

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Forms PTO/SB/08A and PTO/SB/08B, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

It is understood by the Applicants that this paper requires no fee, however, authorization is given to charge any necessary filing fees and any additional fees or credit any overpayment to Deposit Account 23-0455.

Dated: 6-11-2004

Respectfully submitted,

Francis J. Tinney

Registration No. 33,069

Warner-Lambert Company, LLC

2800 Plymouth Road Ann Arbor, MI 48105

Tel. (734) 622-7295

Fax (734) 622-1553

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1

of 5

Complete if Known					
Application Number	10/828,419				
Filing Date	April 20, 2004				
First Named Inventor	Berchielli, et al				
Art Unit	Unknown				
Examiner Name	Unknown				
Attorney Docket Number	PC25684A				

			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	<del> </del> -	US- 4,681,893	07/21/1987	Roth	
	-	<sup>US-</sup> 5,273,995	12/28/1993	Roth	
		US- 5,003,080	03/26/1991	Butler, et al	
		<sup>US-</sup> 5,097,045	03/17/1992	Butler, et al	
		<sup>US-</sup> 5,103,024	04/07/1992	Millar, et al	
		<sup>US-</sup> 5,124,482	06/23/1992	Butler, et al	
		US- 5,149,837	09/22/1992	Buler, et al	
		US- 5,155,251	10/13/1992	Butler, et al	
		<sup>US-</sup> 5,216,174	06/01/1993	Butler, et al	
		<sup>US-</sup> 5,245,047	09/14/1993	Butler, et al	
		<sup>US-</sup> 5,248,793	09/28/1993	Millar, et al	
		<sup>US-</sup> 5,280,126	01/18/1994	Butler, et al	
		<sup>US-</sup> 5,397,792	03/14/1995	Butler, et al	
		us- 5,342,952	08/30/1994	Butler, et al	
		us- 5,298,627	03/29/1994	Butler, et al	
	Ī	<sup>US-</sup> 5,446,054	08/29/1995	Butler, et al	
		<sup>US-</sup> 5,470,981	11/28/1995	Butler, et al	
		<sup>US-</sup> 5,489,690	02/06/1996	Butler, et al	
-		<sup>US-</sup> 5,489,691	02/06/1996	Butler, et al	

	FORE	IGN PATENT DOCU	JMENTS		
Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	7-6
	Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	Τ°
	WO 00/71116 A1	11/30/2000	Kumar, et al		
	WO 01/28999 A1	04/26/2001	Graff, et al		
	WO 01/36384 A1	05/25/2001	Ayalon, et al		L
	WO 01/42209 A1	06/14/2001	Pflaum		
	WO 02/41834 A2	05/30/2002	Brainard		
	WO 02/43667 A2	06/06/2002	Lidor-Hadas, et al		

Examiner	Date	
Signature	Considered	
Signature	00110100100	

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Sheet 2

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Coi		
Application Number	10/828,419	
Filing Date	April 20, 2004	
First Named Inventor	Berchielli, et al	
Art Unit	Unknown	
Examiner Name	Unknown	
Attorney Docket Number	PC25684A	

			U. S. PATENT	DOCUMENTS	
Examiner nitials*	Cite No.1	Document Number  Number-Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevan Figures Appear
	-	US- 5,510,488	04/23/1996	Butler, et al	
		<sup>US-</sup> 5,686,104	11/11/1997	Mills, et al	
		<sup>US-</sup> 5,969,156	10/19/1999	Briggs, et al	
		<sup>US-</sup> 5,998,633	12/07/1999	Jacks, et al	
		<sup>US-</sup> 6,087,511	07/11/2000	Lin, et al	
		<sup>US-</sup> 6,121,461	09/19/2000	McKenzie	
		<sup>US-</sup> 6,126,971	10/03/2000	Mills, et al	
		US- 6,433,213 B1	08/13/2002	Bosch, et al	
		<sup>US-</sup> 6,476,235 B2	11/05/2002	Butler, et al	
		<sup>US-</sup> 6,605,729 B1	08/12/2003	Byrn, et al	
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	t	US-			

		FOREIC	N PATENT DOCL	JMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
	ļ	Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)			· · · · · · · · · · · · · · · · · · ·	₩
		WO 02/43732 A1	06/06/2002	Aronhime, et al		
		WO 02/51084 A1	06/27/2002	Herbig, et al		
		WO 02/057228 A1	07/25/2002	Joy, et al		
		WO 02/057229 A1	06/14/2001	Mathew, et al		
		WO 02/057274 A1	07/25/2002	Srinath, et al		
		WO 02/059087 A1	08/01/2002	Sorsak		

1	Examiner	Date
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1	Signature	Considered

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Sheet 3

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Coi	Complete if Known					
Application Number	10/828,419					
Filing Date	April 20, 2004					
First Named Inventor	Berchielli, et al					
Art Unit	Unknown					
Examiner Name	Unknown					
Attorney Docket Number	PC25684A					

			U. S. PATENT D	OCUMENTS	
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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		FORE	IGN PATENT DOCL	JMENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
	ļ	Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				┾━
		WO 02/083637 A1	10/24/2002	Agarwal, et al		<u> </u>
		WO 02/083638 A1	10/24/2002	Agarwal, et al		
		WO 03/011826 A1	02/13/2003	Reddy, et al		
		WO 03/050085 A1	06/19/2003	Faustman, et al		
		WO 03/070702 A1	08/28/2003	Tessler, et al		
		WO 2004/022053 A1	03/18/2004	Suri, et al		

Examiner Date	
Signature Considered Considered	

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			U. S. PATENT D			
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
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Examiner nitials*	Cite No.1	FOREIGN Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	<u>'</u>
		WO 00/35425	06/22/2000	Kerc		L
		WO 01/76566 A1	10/18/2001	Fox, et al		
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Examiner	Date	
Signature	Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at <a href="https://www.usplo.gov">www.usplo.gov</a> or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08B (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449/PTO **Application Number** 10/828,419 INFORMATION DISCLOSURE Filing Date April 20, 2004 STATEMENT BY APPLICANT First Named Inventor Berchielli, et al. Art Unit Unknown (Use as many sheets as necessary) **Examiner Name** Unknown Sheet Attorney Docket Number PC25684A NON PATENT LITERATURE DOCUMENTS Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of Examiner No.1 Initials\* the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue T<sup>2</sup> number(s), publisher, city and/or country where published. "Handbook of Pharmaceutical Excipients, 3rd Edition", A.H. Kibbe, Editor; Pharmaceutical Press, London, 2000 Takemoto, Masao, et al, "Statins as antioxidant therapy for preventing cardiac myocyte hypertrophy", The Journal of Clinical Investigation, November 2001, Vol. 108, No. 10, pp 1429-1437 Konno, T, et al, Pharm. Bull., 1990, Vol. 38, pp 2003-2007 US Application No. 10/828,079, commonly owned, attorney case number PC25685A US Application No. 10/828,398, commonly owned, attorney case number PC25686A US Application No. 10/828,488, commonly owned, attorney case number PC25825A

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Signature	Compilered	
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<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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